

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
)	
v.)	
)	
SAREPTA THERAPEUTICS, INC.,)	C.A. No. 21-1015 (GBW)
Defendant.)	
)	
)	
)	
SAREPTA THERAPEUTICS, INC., and)	
THE UNIVERSITY OF WESTERN)	
AUSTRALIA, Defendant and Counter-)	<div style="background-color: black; width: 150px; height: 1.2em;"></div>
Plaintiffs)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and)	
NS PHARMA, INC., Plaintiff and Counter-)	
Defendants.)	

**NIPPON SHINYAKU CO. LTD. AND NS PHARMA, INC.’S REPLY IN
SUPPORT OF THEIR MOTION FOR THE ISSUANCE OF A REQUEST
FOR INTERNATIONAL JUDICIAL ASSISTANCE**

I. INTRODUCTION

Plaintiff/Counter-Defendant Nippon Shinyaku Co. Ltd. and Counter-Defendant NS Pharma, Inc. (collectively, “NS”) submits this reply in support of their motion for issuance for letter rogatory. D.I. 274. None of Sarepta Therapeutics’ (“Sarepta”) and University of Western Australia’s (“UWA”) arguments in the responsive brief (D.I. 283) provide grounds to deny the motion.

In opposing NS’s Motion, Sarepta and UWA focus on the timing of NS’s motion, ignoring the parties’ extensive negotiations regarding non-party inventors, Special Master Squire’s recent decision, and UWA’s late refusal to produce documents. The Special Master denied NS’s motion to compel the deposition of Dr. Fletcher on July 7, 2023. NS sought Sarepta and UWA’s consent on July 14, and filed its motion on July 19—only 12 days after the Special Master’s decision. In view of the circumstances, NS’s Motion is timely.

Sarepta and UWA’s characterization of NS’s discovery requests as a “shotgun approach” is similarly misleading. NS had no choice but to engage in third party discovery. As a preliminary matter, the priority applications that eventually issued as the asserted patents were filed 18 years ago, [REDACTED]

The employees who were directly involved are no longer employed by UWA or Sarepta.

More importantly, Sarepta and UWA have refused or been unable to provide relevant, discoverable information. Despite Sarepta’s argument that third party discovery is burdensome and duplicative because it would provide a 30(b)(6) witness designated on topics encompassing former employees’ work, that witness [REDACTED]

[REDACTED] As NS feared, he was [REDACTED]

██████████ NS's decision to seek third party discovery rather than relying on Sarepta to provide party discovery has been fully justified.

Sarepta and UWA also argue that the *Aerospatiale* comity factors weigh in favor of denying NS's request. It is wrong. NS seeks important discovery ██████████. In arguing that NS has ignored alternative methods of obtaining the requested discovery, UWA and Sarepta mischaracterize the discovery they have provided. ██████████

In sum, Sarepta and UWA's attempt to frame NS's request as untimely and insignificant to the issues in the case disregards the parties' extensive negotiations, the Special Master's July 2023 Order, and ██████████

██████████. The Court should grant NS's Motion.

II. ARGUMENT

NS seeks to take evidence from Dr. Sue Fletcher, an inventor on all three patents asserted by Sarepta and UWA. Dr. Fletcher's documents and testimony are important to central issues in the case, namely NS's defenses and counterclaim of inequitable conduct. NS timely sought this Letter of Request after Special Master Squire denied its motion to compel the deposition of Dr. Fletcher. Moreover, the *Aerospatiale* factors favor granting NS's request.

A. NS's Motion is Timely

Sarepta and UWA's argument that "NS has known since the start of this litigation that if it wanted discovery from Dr. Fletcher, it would need to seek such discovery through a Letter of Request" is disingenuous. Resp. 8. The cases cited by Sarepta and UWA are inapposite. This is not the case where NS sat idly by and did nothing. NS has pursued a deposition of Dr. Fletcher

and discovery from UWA for months to no avail, culminating in a motion before the Special Master.¹ *C.f. Barton v. RCI, LLC*, Civ. No. 10-3657, 2014 WL 12633500 at *3 (D.N.J. Mar. 17, 2014) (movant did not even express desire for deposition until three months before close of discovery); *Roc Nation LLC v. HCC International Insurance Co., PLC*, 19 Civ. 554 (PAE), 2020 WL 3170886, at *1 (S.D.N.Y. June 15, 2020) (request made two months after close of discovery “without any explanation for why it [] delayed bringing its [] request for letters rogatory”); *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, Civ. Nos. 12-3289 (PGS), 12-3324 (PGS), 2013 WL 12203112, at *4 (D.N.J. June 7, 2013) (movant sought letter of request of “non-party prior art inventors” two months before fact discovery closed).

The parties have engaged in extensive negotiations regarding discovery from Dr. Fletcher (an inventor of the UWA patents) and Dr. Takada (an inventor of the NS patents). Neither is an employee of a party (Dr. Takeda is an employee of NCNP, a co-owner of the NS patents) and both reside outside the United States. NS has requested information related to Dr. Fletcher from counsel for Sarepta and UWA—who also represent Dr. Fletcher—since last fall and asked that they accept service of a notice of deposition. In March 2023, counsel responded that although UWA could not force Dr. Fletcher to participate, counsel would “follow up once we have more information on [their client, Dr. Fletcher’s] potential availability.” Exhibit A.

In April 2023, Sarepta and UWA changed course and said that it was “**premature**” to discuss discovery from Dr. Fletcher until NS “provides deposition dates for Drs. Takeda and Nagata and also produces documents in its possession from NCNP.” Exhibit B. On June 13, 2023,

¹ The Special Master denied NS’s motion to compel because he found that [REDACTED] D.I. 254 at 12. The Special Master did not address Sarepta and UWA’s arguments that the discovery was irrelevant.

the parties submitted a joint letter to the Special Master requesting a discovery conference related to whether NS should be compelled to produce Dr. Takeda for deposition and Sarepta and UWA should be compelled to produce Dr. Fletcher for deposition. On July 7, 2023, Special Master Squires issued a written decision denying NS's motion to compel the deposition of Dr. Fletcher because [REDACTED]

[REDACTED] D.I. 254. NS thus proceeded with seeking discovery from Dr. Fletcher through this Motion for the Issuance of Letter Rogatory.

Fact discovery closed July 27, 2023. Notwithstanding this deadline UWA has [REDACTED]

[REDACTED] The Parties also entered into a stipulation that allows the parties to take depositions out of time and to extend the dates for expert discovery and dispositive motions. D.I. 268. The Court adopted this stipulation. D.I. 269. Thus, granting NS's request will not necessitate moving the current dispositive motion deadlines or trial dates.

Separately, NS conveyed the Court's signed Letter of Request related to Ms. Abbie Adams and Ms. Penny Meloni (D.I. 239) to the Supreme Court in Australia for execution and requested that the depositions take place no later August 25, 2023. The Court has set a hearing date of August 3, 2023. NS will endeavor to take the deposition of Dr. Fletcher during the same time period as Ms. Adams's and Ms. Meloni's deposition, eliminating Sarepta and UWA's concerns of further delay.

B. *Aerospatiale* Factors Favors Granting NS's Request

Sarepta and UWA argue first that NS's alleged delay in seeking this Letter of Request outweighs any alleged importance to the discovery sought. (Resp. at 10). As described *supra*, any alleged delay in NS's request for seeking a Letter of Request is due to UWA and Sarepta's

indication it would “follow up” with Dr. Fletcher’s availability for a deposition and then refusing to make Dr. Fletcher available for deposition. Moreover, their suggestion that discovery from Dr. Fletcher is of minimal importance directly contradicts Sarepta and UWA’s arguments that they submitted to the Special Master [REDACTED]

[REDACTED] Sarepta Mot. to Compel 3. As NS explained in its opening brief, the discovery sought from Dr. Fletcher is essential to NS’s defenses and counterclaim of inequitable conduct.

NS has not been able to secure the requested information from Sarepta, UWA, or Dr. Wilton, the 30(b)(6) witness designated on topics including UWA’s DMD and exon skipping research [REDACTED]

Although Sarepta urges that it has produced [REDACTED] Dr. Fletcher did not author a single lab notebook that it produced. Nor does [REDACTED]

[REDACTED] Thus, if UWA and Sarepta have no documents related to Dr. Fletcher’s involvement in the research and testing of ASOs to induce exon skipping for the treatment of DMD, NS has no other available means to obtain this information. *See Arcelik A.S. v. E.I. Dupont de Nemours & Co.*, 856 F. App’x 392 (3d Cir. 2021) (there were no other available means to obtain information where the related domestic entity “represented that it had no responsive documents.”). Sarepta’s 30(b)(6) witness testified that [REDACTED]

As detailed in NS’s opening brief, Dr. Wilton’s testimony [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See *Dyson, Inc. v. SharkNinja Operating, LLC*, No. 1:14-cv-0779, 2016 WL 5720702 at *2 (N.D. Ill. Sept. 30, 2016).

Sarepta's arguments that NS's request is overbroad is similarly unavailing. NS seeks testimony and documents from Dr. Fletcher related to her research in ASOs to induce exon skipping. These directly relate to central issues in this case, the validity and enforceability of the asserted UWA patents. *See, e.g., Luminati Networks Ltd. v. Teso LT, UAB*, No. 2:19-CV-00395-JRG, 2020 WL 6815153, at *1 (E.D. Tex. Oct. 28, 2020) (finding specificity factor weighed in favor of granting motion for issuance of letters rogatory where testimony sought related to claims in case); *see also Ingenico Inc. v. Ioengine, LLC*, No. 18-826-WCB, 2021 WL 765757, at *4 (D. Del. Feb. 26, 2021) (describing as "sweeping" a request from two non-inventors for "all documents related to [the inventor and another individual] and **any entities now or once affiliated with them . . . or their agents or representatives**" (emphasis added)).

Further, Sarepta and UWA have not explained why Australian sovereignty or interest could be at risk were the Court to grant NS's Motion. As explained in NS's opening brief, Australia "will ultimately decide about . . . specific questions" as it is doing with regards to Ms. Adams' and Ms. Meloni's testimony. *Arcelik A.S. v. E.I. Dupont de Nemours & Co.*, 856 F. App'x 392400399 (3d Cir. 2021). Because Australia has "the power to tailor the requests [it] will enforce[,] courts have declined to find that this factor weighs against issuance of a letter of request under the Hague Evidence Convention." *McCarthy v. Johnson*, No. 21-mc-4 (GMH), 2022 WL 16834019, at *8 (D.D.C. Nov. 9, 2022).

As explained *supra*, four of the five *Aerospatiale* factors weigh in favor of Granting NS's Motion. Although the requested evidence relates to information that originated outside of the United States—Dr. Fletcher performed her work in Australia—this is “overcome by the fact that there [are] no alternative means for [NS] to obtain the information” and because her testimony is vital to NS's defenses and inequitable conduct counterclaim. *See Arcelik*, 856 F. App'x at 399. The Court should therefore grant NS's Motion.

III. CONCLUSION

For the foregoing reasons, NS respectfully requests that the Court grant its Motion and that the Court sign and issue the letter of request. Once the Court has done so, counsel for NS shall convey the signed letter to the Supreme Courts in Australia for execution.

Dated: July 31, 2023

Respectfully submitted,

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